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The purpose of this randomized clinical trial is to study the impact of an advanced practice nurse on the cost of care and quality of life for women newly diagnosed with breast cancer. The control group receives standard medical care while the experimental group receives standard medical care plus advanced nursing care. The number of participants who have been enrolled in this study is 146. Attrition (10%) has occurred at one half the projected rate and refusal to participate (29%) has been 11% lower than anticipated. Ineligibility due to a previous diagnosis of cancer and treatment at a different treatment site after diagnosis has been higher than anticipated. Modifications in the proposal have been submitted to increase our sample size. USAMRMC approval is pending. The cost model has been developed and costs identified within each of the categories. Data collection and entry are proceeding with a participant response rate of 94%. High data reliability and internal validity have been established.

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Louis J. Pitt 10/23/96

PI - Signature Date

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INTRODUCTION

NATURE OF PROBLEM AND BACKGROUND OF PREVIOUS WORK

Breast cancer accounts for almost one third of all cancers in women in the United States (US). Greater than 184,000 new cases will be diagnosed in 1996 alone. More than 44,000 women will die of breast cancer this year.[1] Cost-effective methods to manage breast cancer patients while continuing to achieve quality outcomes is a major US public health goal.

As costs decrease, it is unclear if quality outcomes are being maintained. In addition, factors including access to care, intricacy of the health care system, numerous caregivers, complexities of the diagnostic tests and procedures, and technical components of treatment can overwhelm patients and result in compromised quality outcomes.

An Advanced Practice Nurse (APN) could serve as a facilitator to ease the breast cancer patient's way through the health care system providing quality care in a cost-effective manner. The former Office of Technology Assessment (OTA) of the US Congress conducted a comprehensive review of 286 studies on the cost and effectiveness of APNs. Their findings from this review indicated that within the APN's area of competence, they communicate better with patients, concentrate more on prevention, and provide more education than physicians. Patient are satisfied with care, access to care is less complicated, and the costs of care are less with the interventions of the APN.[2]

Additional studies including those which focused on lung cancer patients, low birthweight infants, MI patients, HIV-infected individuals, children with chronic diseases, and hospitalized elderly, have demonstrated the effectiveness of advanced nursing care with results of improved outcomes and reduced health care costs, but no one has focused on women with breast cancer. [3-10]

PURPOSE OF PRESENT WORK AND METHOD OF APPROACH

The purpose of this study is to test the following hypotheses:

- Women with newly diagnosed breast cancer who receive advanced nursing follow-up care/interventions will have a lower cost of care than patients who do not receive advanced nursing care.

- Women with newly diagnosed breast cancer who receive continuity of care through advanced nursing care/interventions across the various health care settings will achieve a better quality of life than patients who do not receive advanced nursing care.

The method of approach for this study is a randomized clinical trial to test these hypotheses using Brooten's model,[11] with modifications, to provide the framework for studying cost and quality of patient outcomes with the interventions of APNs.

BODY

Previously Reported Work

Preparation to Begin Study

As defined in the statement of work, hiring of staff, determination of APN charges, preparation of the data collection tools, and initial as well as continuing education of all participating staff has occurred as previously reported in the annual report for the period of October, 1994 - September, 1995.

Cost Analysis Model

The Cost Analysis Model has been completed (Appendix A). It consists of two main branches (total charges and total reimbursement) which continually divide to take into account the desired outcomes of the analysis of the study such as in-system versus out-of-system costs, and cancer related versus non-cancer related costs. The final extension of this model creates the cost categories of hospitalizations, emergency room visits, outpatient services, and non-charge estimates. The costs included within each of these final categories has also been identified. (Appendix B).

Accrual, Intervention, and Data Collection

Women with a newly diagnosed breast cancer are identified through positive pathology reports and referral by their physicians. They are then approached about their participation in the study, eligibility criteria are reviewed, informed consent is obtained and participants are randomized to one of two groups. Women in the control group receive the standard care which they would receive in the clinic, hospital, or patient's home. Women enrolled in the experimental group have an APN who begins follow-up immediately and continues follow-up for two years. All participants are asked to complete quality of life questionnaires at intervals of one week, one, three, six, twelve, eighteen, and twenty four months as well as a patient diary (schedule of their episodes of care) for the two year period.

Current Work (October 1995-September 1996)

Accrual Status

Accrual status to date is summarized in Table 1 as follows:

OCTOBER 1, 1994 - SEPTEMBER 30, 1996	Number of patients
Newly diagnosed breast cancer patients	419
Referred	361 (86%)
Eligible	206 (57%)
Refused	60 (29%)
Participants enrolled from eligible	146 (71%)
Lost to attrition	15 (10%)
Total participants	131

Four hundred nineteen women were diagnosed with breast cancer within our system of care during the first two years of study (October 1, 1994 - September 30, 1996). One hundred fifty-five were ineligible with sixty refusing to participate. The refusal rate (29%) is lower than anticipated, when compared with Hughe's reported refusal rate of 40% at the time of diagnosis.[12] Attrition (10%) has occurred at a rate of one half the projected rate.

Ineligibility is higher than anticipated. Reasons for study ineligibility during the past year include: previous diagnosis of cancer (n= 37), going outside the approved site of the study for care after diagnosis (n=28), inability to enroll within two weeks after diagnosis (n= 12), comorbidity which limits functional ability (n=7), inability to give informed consent (n=3), inability to complete questionnaires (n=3), severe psychiatric illness (n= 2), and inability to read or write English (n=1).

A modification to the study which increased the registration time of the subjects from one to two weeks following diagnosis was approved 10/16/95. This modification has increased our rate of enrollment from 6.8 participants/month to 7.3 participants /month.

Changes in health care delivery are occurring within our system. The diagnosis of breast cancer is made at our site with an increasing number of women choosing another hospital for treatment. Another change is the addition of 70,000 patients to our system of care beginning January 1, 1997. Based on these changes, we have written and submitted two further modifications to this study.

The first modification would allow enrollment of women who are being treated at a second hospital site. The second modification would extend our study period from 9/30/98 to 9/30/99. These modifications will increase our sample to 100 subjects in each group which using an alpha of .05 and statistical power of .8, will produce statistically significant results.

Although we are requesting extension of the study period, we are not asking for additional funding. Approval of the additional study site and extension of our period of study has been approved by the IRB both at our current and proposed study sites and by our grant administrator. Approval from the USAMRMC is pending.

APN Intervention

Follow-up care and interventions of the APN are based on Brooten's work [11] and the standards of advanced practice in oncology nursing.[13] It includes coordination of care, assessment and monitoring of symptoms, direct care, patient and family education, consultation with other health care services, utilization of current research findings, and establishment of standards of practice. Care is individualized to the patient and family needs, based on the expressed needs of the individual, the assessment of the APN, and other health care providers' evaluations. A detailed description of the standard APN follow-up care is listed in Appendix C.

Data Collection and Entry

Collection of data is proceeding as outlined in the protocol. The response rate for the sets of the questionnaires (week 1, month 1, month 3, month 6, and monthly 12) for participants currently enrolled on the study is 94% (431/460). The data from the questionnaires has been continually entered into their appropriate databases as the sets are returned.

Collection methods were set up to gather the specific cost information from the hospital's billing system (Phamis), the clinic's billing system (Med.I.C.), and independent physicians affiliated with the hospital. Phamis is a health information management system and serves as the patient information data repository for the hospital. It runs on a Tandem midrange computer and consists of a variety of modules including encounter/visit management, ancillary management, nursing management, medical record management, patient registration, laboratory results reporting, pharmacy management, and patient accounting. Med.I.C. is a clinical management application that runs on an IBM 3090 developed by the Management Information System's (MIS) staff at Park Nicollet Clinic. It assumes the same role as Phamis in the clinical setting.

The collection methods for Phamis and Med.I.C. involve querying each system by the patient's chart number and outputting the desired data into a file with a delimited text format. This file is then imported into the correct database. The independent physicians are providing their cost information through their billing systems and this data is entered into a database. In order to carry out the planned analyses the detailed cost data must then be formed into a composite database summarizing in-system, out-of-system, cancer-related, and non-cancer-related costs for each patient in order to carry out the planned analyses. A mock cost dataset was used to create and test an algorithm (SAS) for reducing the multiple records to an analyzable dataset containing only 8 records per person. These 8 records include charge and reimbursement amounts for each of the four categories listed above.

Non-charge estimates are collected from APN logs and patient diary data. The data collected in the APN logs will be applied to a standardized APN intervention estimate. This APN intervention estimate is determined by using mean salary and benefits to calculate a per minute cost for time spent with each patient in the intervention arm. The other estimates will not have charges assigned to them and will be reported separately.

The collection methods of treatment and tumor information are also established. This information is abstracted from the hospital's oncology registry. The registry is a data system designed for the collection, management and analysis of data on persons with the diagnosis of cancer.[14] The data is abstracted through a query of the registry's database and exported as a delimited file. This file is then imported into the correct database.

Databases have been developed and currently exist for the entry of questionnaire information, diary information, APN log data, treatment and tumor information, and the cost information from participating physicians, clinics, and hospital(s). These databases are related to one another via a variety of relational variables. These relational variables are unique identifiers for each patient in Phamis, Med.I.C., and the oncology registry and are indexed to the patient's study identification (ID) in a database designed specifically for that purpose. Data dictionaries have also been created to identify the variables in each of these databases.

The analysis of the data will begin in month 48 of the current statement of work or month 56 of the proposed work agreement.

Data Quality

The reliability of the data collected from the patient diary was evaluated to determine areas of strength and weakness. Each ledger-format diary allows patients to record data about episodes of care and participant/family members days lost from work and child care. Responses (n=18) from the first patient diaries (0-6 months) were compared to the hospital-clinic computer system to determine validity. The mean perfect agreement was

9.06 (standard error (steer = 0.366) on a binary score of 11 items. The intervention group (score 9.09, stderr=0.495) had a greater number of patients with perfect agreement (correct physician/nurse name and correct date) for the categories including: primary doctor visits (8/11 vs. 4/7), surgery visits (4/11 vs. 2/7), plastic surgery visits (11/11 vs. 6/7), other visits (7/11 vs. 2/7), and urgent care visits (11/11 vs. 6/7). The control group (score 9.0 stderr 0.577) had a greater number of patients with perfect agreement for the hospitalizations (7/7 vs. 10/11), medical oncologist visits (4/7 vs. 5/11), nursing visits (6/7 vs. 8/11), nurse practitioner (6/7 vs. 9/11), home care visits (7/7 vs. 10/11), emergency room visits (7/7 vs.10/11) and treatment category (6/7 vs. 7/11). Individual visits to health professionals and the overall treatment categorization show the most discordance. The patient diaries report fewer visits compared to the hospital-clinic computer system. Our long-term diary is a useful data collection tool (less than 10% disagreement) for breast cancer patients for homecare visits, hospitalizations, urgent care or emergency room visits. It can provide data about support group attendance, out-of-system hospital and clinic visits, child care use and days of work lost. This information is unavailable through other common data sources and is necessary to conduct the planned cost-benefit analysis.

CONCLUSIONS

Women with a newly diagnosed breast cancer who meet the study criteria, are participating in the study at a higher than initially projected rate. The refusal rate is 11% less than projected and attrition is one half of the projected rate. The questionnaire response rate is 94%. Comparisons of data from multiple sources indicate high reliability and internal validity.

The Cost Analysis Model is completed and is providing the framework to collect patient charges, reimbursement, and nonbillable costs. The APN intervention is being successfully implemented. Standard follow-up is well-defined with additional cares based on the patient's needs. Results of the completed data have not been analyzed but many anecdotal responses of the participating women, their health care providers, and other patients not participating in this study indicate positive outcomes.

Ineligibility of women has contributed to a lower than expected rate of enrollment, but protocol changes have been recommended to address this issue. These changes are feasible and will not alter the scientific merit of the study. With the USAMRMC's approval of the addition of another study site and another year of study (no additional funding requested), we will meet the work agreement as defined in our statement of work.

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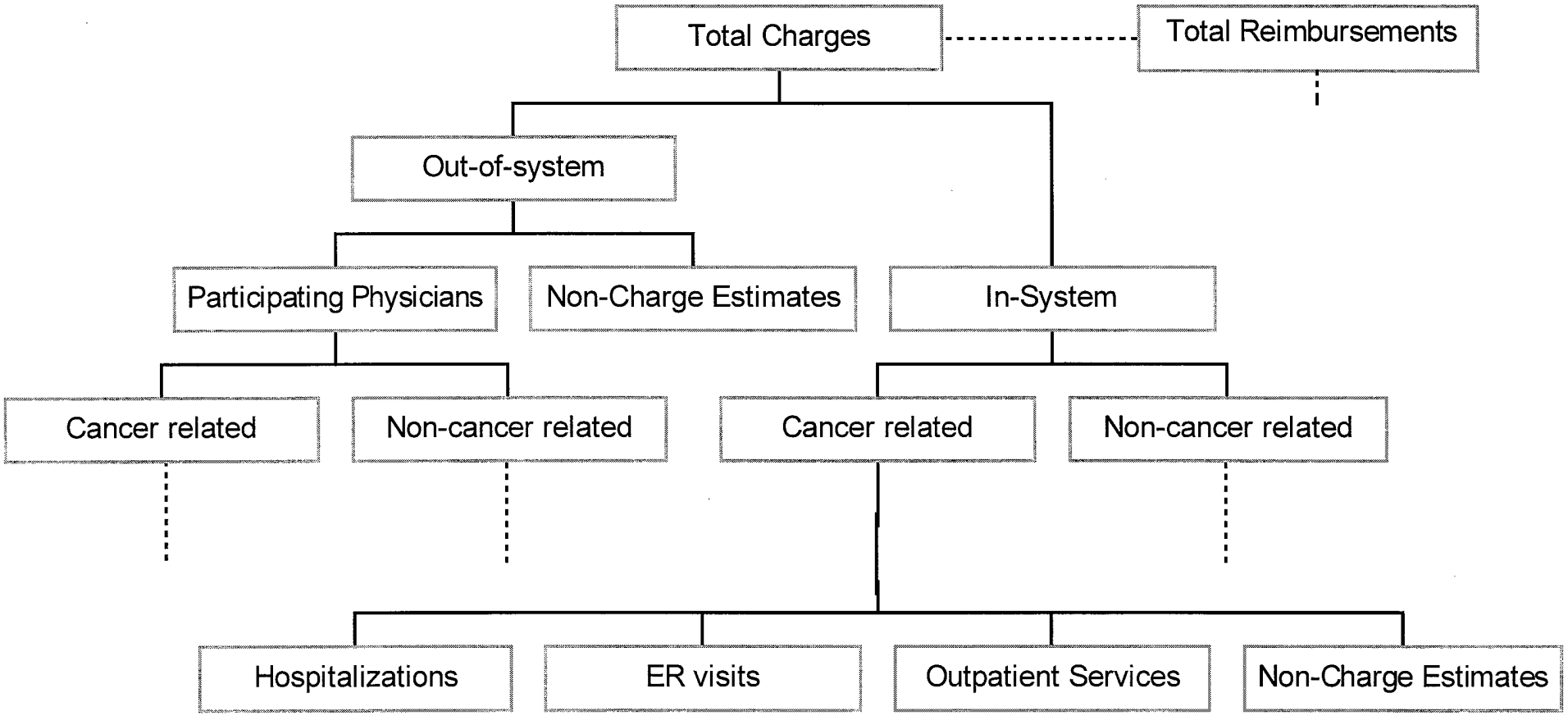
Cost Model



Appendix A

Cost Model

Identification of Costs Included Within Each Category

1. Hospitalizations

A) Inpatient

a) Provider procedures and services
b) Room utilization
c) Radiologic procedures
d) Laboratory tests
e) Supplies
f) Medications; Drugs
g) Rehab services (if needed)
h) ER services (if needed)
i) Professional fees

Nurse anesthetist
EKG reading by cardiologist
Park Nicollet physician fees

B) 23 hr

same as inpatient charges

C) One day surgery

same as inpatient charges

2. Emergency room visit charges

A) Provider procedures and services
B) Radiologic procedures
C) Laboratory tests
D) Supplies
E) Medications; Drugs
F) ER professional fees
Park Nicollet physician fees

3. Outpatient service charges

A) Park Nicollet clinic visit charges

a) Provider procedures and services
b) Radiologic procedures
c) Laboratory tests
d) Supplies
e) Medications; Drugs

B) Outpatient hospital service charges

a) Chemotherapy visit charges

i) Provider procedures and services
ii) Radiologic procedures
iii) Laboratory tests
iv) Supplies
v) Medications; Drugs

b) Radiation therapy visit charges

same as chemotherapy charges
Radiation oncologist fees

c) Home care visit charges

same as chemotherapy charges

d) Rehabilitation visit charges

same as chemotherapy charges

4. Non-charge estimates

A) Advanced Practice Nurse intervention

a) Patient visits
b) Home care visits
c) Telephone calls
d) Administrative
e) Travel

B) Rehabilitation services

a) Breast cancer support groups
b) Other support groups
c) Chaplain
d) Psychologist (out-of-system)
e) Social worker
f) Sex therapist (out-of-system)
g) Dietitian

C) Telephone calls

a) Nurse
b) Physician

D) Child care / lost work time
E) Hospitalizations (out-of-system)
F) Home Care visits (out-of-system)
G) Referring physicians (out-of-system)

Standard APN
Follow-up Care

	PHASE I INTRODUCTION		PHASE III FOLLOW-UP IF NO TREATMENT
Frequency	**Pre-surgical meeting @ 0-7 days**	**Frequency**	Radiation, Chemo, Surgery, Plastic Surgery
	Introductory meeting		**Weekly contact for status**
1visit; 1 call	Explanation of BCNC role & availability	weekly	Education, support and assessment
1visit; 1 call	Needs assessment form	x 2-24wks	Pain
1visit; 1 call	Decision making process	x 2-24wks	ROM
1visit; 1 call	Physical assessment form with Hx (PRN)	x 2-12wks	Seroma
hospital visit	Give pt. copy history/current meds	x 2-12wks	Necrosis
hospital visit	Library information given	x 2-26 wks	Oral intake (especially with chemo)
hospital visit		x 2-12wks	Infection
	Follow-up-up plan:	ongoing	Fatigue
	Tentative plan of care:	x 2-26 wks	Prosthesis Information
	Obtain arm measurements bilaterally	x 2-26 wks	Blood counts
daily callx1-2wks	Calendar	x 2-26 wks	**Psychosocial support**
wkly callsx6-8	Accompany to MD visits		Mood
1 visit	Next contact with BCNC (date)	ongoing	Coping
ongoing	Contact during hospitalization	ongoing	Energy level
ongoing	Contact during outpatient visit	ongoing	Referral to Social Services PRN
			Referral to Support Groups in community
1-2 visits	**PHASE II POST OP**	ongoing	**BCNC support during any/all visits**
1-3x/week	**Home visit post-op 24-48 hrs**	ongoing	surgeon, plastics, oncologist, radiation
	Telephone contact during 1st 3-5 days		
	Education	ongoing	**Follow-up visit @ 4-6 weeks (all pts)**
x 1	Signs of infection/inflammation		Physical assessment
daily x 7	Temp		Arm measurements
daily x 7	JP Stripping /Drainage / leakage/	x1-2 visits	Review signs/symptoms of lymphedema
daily x 7	Incisional Pain	PRN	Body image-looked in mirror?
daily x 7	Swelling	x1 or PRN	Prosthesis
daily x 7	Redness	x1 or PRN	Sexuality
daily x 7	Arm ROM/ pain / burning	x1 or PRN	Back to work or normal activity yet?
daily x 7	General well-being	x1 or PRN	Told others?
daily x 7	Mood	1-24 wks	Family
daily x 7	Fatigue	1-4 wks	Friends
daily x 7	Energy level	1-4 wks	Co-workers
daily x 7	Appetite	1-4 wks	Support group?
daily x 7	Comfort/pain control/ constipation	1-24 wks	**Follow-up with oncologist**
weekly	Coping with life and home	ongoing	Support
weekly	Spouse/significant other	ongoing	Treatment discussion
weekly	Family issues	ongoing	Options
weekly	Children	ongoing	Reinforce education
weekly	Child care	ongoing	Wigs
weekly	Job/career	2-24wks	Cosmetics/hair care
weekly	Housework	ongoing	Fatigue management
X1	**Have they met with reach to recovery**	ongoing	Hot flashes and management
weekly	Exercise/ review with pt /	ongoing	**Follow-up with Plastic Surgeon**
x2	Prosthesis	ongoing	Monitor for necrosis
	Follow-up surgeon visit date?	ongoing	Monitor for infection
5 visits/ ongoing	**Medical plan of care:**	ongoing	Assess for normal ADL's
	RT	ongoing	Pain control with saline expansion
	Chemo	ongoing	Plan for secondary surgery PRN
	Additional Surgery		
	Next FU visit scheduled?		

Standard APN
Follow-up Care

	PHASE III TREATMENT MANAGEMENT		PHASE IV FOLLOW-UP CARE
Frequency		**Frequency**	
monthly FU	**Tamoxifen**		Telephone contact every other wk x 4
0-2 yrs	Side effects: Hot flashes, weight,		(every week x 4 if no treatment; then qow
	mood swings, endometrial ca risk	ongoing	Monthly FU phone calls or visits for all pts
	GYN evaluation if spotting	ongoing	Lymphedema FU every 3 mos x 4; then q 6
daily x1-3	**Chemo: Call day 1,2,3**	ongoing	BSE instruction with return demo PRN
weekly 0-32	Assess nausea, fatigue, diet, activity,		give shower cards, stickers
& monthly	diarrhea, constipation, mouth sores	ongoing	Mammogram scheduled annually
	Blood counts	ongoing	Stress importance of BSE and FU care
	Educate regarding plan & ttment delays	monthly	**ISSUES: support, assess and educate**
FU weekly	**Radiation Therapy:**	ongoing	Diet
0-10 weeks	Assess skin reaction, fatigue,	ongoing	Exercise
	blood counts	ongoing	Weight
0-10 weeks	Educate regarding ttment plan and FU	ongoing	Hot flashes
		ongoing	Sexuality
monthly	**Educational reinforcement**	ongoing	Pregnancy
ongoing	**Frequency of healthcare visits:**	ongoing	Work Issues
ongoing	Strategy for coping	ongoing	Menopause
ongoing	Activity adjustment	ongoing	Insurance coverage
ongoing	Fatigue management	ongoing	Medication cost
		ongoing	Venous access device management
monthly	**Activity of daily life**	ongoing	Late treatment effects
ongoing	Ability to perform ADL's	monthly	**Health Promotion**
ongoing	Appearance	ongoing	Quit smoking
ongoing	Fatigue	ongoing	Diabetic control
ongoing	Energy level	ongoing	Assess hypertension
ongoing	Change from precancer level of activity	ongoing	Dietary modifications
ongoing	Diet adjustment	ongoing	Stress reduction
ongoing	Oral rinse and mouth care	monthly	**Complementary therapies**
ongoing	Fluid intake	ongoing	Stress management
ongoing	Monitor output	ongoing	Imagery
ongoing	Taste changes	ongoing	Positive thinking
ongoing	Weight gain/loss	ongoing	Support groups
ongoing	Social adjustment	monthly	**Recovery**
ongoing	Sick leave availability	ongoing	Taking control/proactive
ongoing	Child care issues	ongoing	Fear of recurrence
ongoing	Transportation to treatment	ongoing	Coping
ongoing	Cooking	ongoing	Spirituality
ongoing	Cleaning	ongoing	Hope
ongoing	Laundry	monthly	**Psychosocial assessment:**
ongoing	Shopping	ongoing	Kids
ongoing	other	ongoing	Sex
monthly	**Physical side effects**	ongoing	Work
ongoing	Skin care:	ongoing	Home
ongoing	Rashes	ongoing	Reconstruction
ongoing	Incision	ongoing	Future plans
ongoing	Dryness	ongoing	Social Services referral PRN
ongoing	Neuropathy		
ongoing	Status of surgical site		

ACRONYM AND ABBREVIATION DEFINITIONS

APN	-	Advanced Practice Nurse
EKG	-	Electrocardiogram
ER	-	Emergency Room
HIV	-	Human Immunodeficiency Virus
MI	-	Myocardial Infarction
MIS	-	Management Information Systems
OTA	-	Office of Technology Assessment